K070289

MAY - 4 2007

SUMMARY & STATEMENT OF COMPARISON

(as per 21 CFR 807.92c)

1) Submitted by:	Hugh Palmer, Official Correspondent Acquamed Technologies, Inc. 33 West 480 Fabyan Parkway, Unit 105 West Chicago, IL 60185 (Tel: 630-232-8704)
2) Establishment Registration No:	3004691767
3) Date Prepared:	01/15/07
4) Product Proprietary Name:	Acquaseal Benz
5) Device Common Name:	Resin Tooth Bonding Agent
6) Device Classification Name:	Agent, Tooth Bonding, Resin (21 CFR 872.3200)
7) Device Class:	Class II (KLE)
8) Substantial equivalence:	The Acquaseal Benz manufactured and marketed by Acquamed Technologies, Inc., is substantially equivalent to the Legally Marketed Predicate: Hema-Benz (K953405) originally manufactured by Health-Dent, Intl. (Refer to section VI of this submission.)

The 510(k) Substantial Equivalence Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1) The Acquaseal Benz and the Hema Benz listed above have the same intended use, that being as varnish on sensitive teeth, over exposed dentin on exposed dentin on roots.

2) The technological characteristics for this product are the same as the predicate device listed as the ingredients are the same. No significant variation has been implemented.

3) Descriptive information per the table noted below further show that the materials from the listed predicate devices are substantially equivalent as they are used for the same purpose and have same properties.

4) As noted above, the Substantial Equivalence Decision-Making Process Chart was used.

See below for a comparison table showing similarities and differences from the predicate

devices listed supporting substantial equivalence.

Similarities:

AcquaSeal Benz	Legally Marketed Predicate: Hema-Benz (K953405)
Hydrophilic liquid containing Hydroxyethyl-methacrylate (HEMA), Fluoride and Benzakonium Fluoride.	Hydrophilic liquid containing Hydroxyethyl-methacrylate (HEMA), Fluoride and Benzakonium Fluoride.
Indicated as a bonding agent for dental restoration.	Indicated as a bonding agent for dental restoration.
Desensitizing; Mechanically occludes the dentinal tubules due to polymerization to decrease hypersensitivity.	Desensitizing; Mechanically occludes the dentinal tubules due to polymerization to decrease hypersensitivity.

Differences:

AcquaSeal Benz	Legally Marketed Predicate: Hema-Benz (K953405)
As the predicate, the Acquaseal Benz is indicated dental restorative procedures and desensitization, but is also indicated for cervical and hygiene procedures as the liquid is applied with a cotton swab tipped device.	As this product's predecessor, Hema-Glu (K951220) the Hema-Benz is indicated for dental restoration and desensitization. Both of these products are noted for use with adhesive bonding systems and crown and bridge luting agents to eliminate post treatment sensitivity. They are also recommended for the treatment of dentin or cementum sensitivity following root planning and periodontal surgery and can be used prior to placing amalgam restorations. The above referenced products were developed to be applied with a cotton pellet.

Conclusion:

Per the review noted above in accordance with the guidance document, the Acquaseal Benz is found to be substantially equivalent to the identified predicate device.

Signature: **Date:**
Hugh Palmer, Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acquamed Technologies, Incorporated
C/O Ms. Tammy Lavery
Regulatory Affairs, Senior Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

MAY - 4 2007

Re: K070289
Trade/Device Name: Acquaseal Benz
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Codes: LBH and KLE
Dated: April 25, 2007
Received: April 26, 2007

Dear Ms. Lavery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

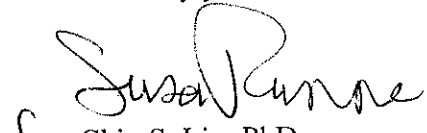
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070289

Device Name: Acquaseal Benz

Indications for Use:

The Acquaseal Benz is indicated for dental restorative, hypersensitivity, cervical, and hygiene procedures.

Prescription Use X **AND/OR** **Over-The-Counter Use**_____

(Per 21 801 CFR Subpart D) **(Per 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...n of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number K070289

(Posted November 13, 2003)